



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-1961]

Advancing Premarket Safety Analytics Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is requesting comments on the topics discussed at a public workshop entitled “Advancing Premarket Safety Analytics Workshop” held on September 14, 2022. The purpose of the public workshop was to present FDA’s work and perspective on premarket review of safety data.

DATES: Either electronic or written comments on this public workshop must be submitted by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. See the SUPPLEMENTARY INFORMATION section for information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment

does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2022-N-1961 for "Advancing Premarket Safety Analytics Workshop." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT

CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Christopher Smith, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6230, Silver Spring, MD 20993, 301-796-4851, christopher.smith2@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Because of a lack of standardization of safety data analysis and visualization, inconsistencies have been noted in how adverse events are defined, categorized, analyzed, and presented in marketing applications. The FDA Center for Drug Evaluation and Research’s (CDER’s) Office of New Drugs (OND) led the development of two documents to facilitate

internal review of safety data. The first document, “FDA Medical Queries,” provides a standardized approach to group preferred terms of adverse events using “Medical Dictionary for Regulatory Activities” (MedDRA) terminology. The second document, “Standard Safety Tables and Figures Integrated Guide,” provides standardized methods for visualization of clinical trial safety data into tables and figures. FDA values transparency and collaboration with external stakeholders; therefore, both documents are available for public comment through the docket.

II. Topics Discussed at the Public Workshop

At the public workshop entitled “Advancing Premarket Safety Analytics Workshop,” CDER’s OND presented its work and perspective related to safety analytics. The workshop provided presentations from FDA staff on the two documents “FDA Medical Queries” and “Standard Safety Tables and Figures Integrated Guide ” (meeting materials available at <https://healthpolicy.duke.edu/events/advancing-premarket-safety-analytics>). The workshop also included panel discussions with industry representatives on “Stakeholder Perspectives Exploring Premarket Adverse Event Grouping” and “Examining Strategies for Adverse Event Analysis.” FDA documents were intended as a starting point for broader discussions on best practices and innovative approaches for advancing premarket safety signal analytics. We are also seeking comment on the topics discussed at the workshop.

Dated: October 31, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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